

Lamotrigine Orally Disintegrating Tablet

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Lamotrigine Orally Disintegrating Tablet (ODT) is an anti-epileptic medication used to help control certain kinds of seizures or to treat bipolar disorder. There are several immediate release formulations of this medication that can be used such as immediate-release tablets, chewable tablets, and orally disintegrating tablets. For members who cannot swallow a pill, lamotrigine chewable tablet is a viable alternative option to Lamotrigine ODT.

Definitions

"**Anti-epileptics**" refers to medications used to treat seizures.

"**Epilepsy**" is a chronic neurological disorder characterized by the tendency to have recurrent unprovoked seizures. Two or more of these seizures occurring more than 24 hours apart can be indicative of this syndrome.

"**Bipolar Disorder**" is a mental health condition marked by extreme mood swings that include episodes of depression (lows) and mania (highs). It is a long-term, or chronic, condition that requires ongoing management.

Medical Necessity Criteria for Initial Authorization

The Plan considers **Lamotrigine ODT** medically necessary when **ALL** the following criteria are met for the applicable indication listed below:

For the treatment of Seizure Disorders:

1. The member is 2 years of age or older; **AND**
2. The member has ONE (1) of the following diagnoses:
 - a. partial-onset seizures; **or**
 - b. primary generalized tonic-clonic (PGTC) seizures; **or**
 - c. generalized seizures of Lennox-Gastaut syndrome; **or**
 - d. absence seizures; **AND**
3. The member is unable to use or has tried and failed BOTH of the following:
 - a. Lamotrigine immediate-release; **and**
 - b. Lamotrigine chewable tablet; **AND**
4. Lamotrigine ODT is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature; **AND**
5. Clinical chart documentation is provided for review to substantiate the above listed requirements.

For the treatment of Bipolar Disorder:

1. The member is 18 years of age or older; **AND**
2. The member has a diagnosis of bipolar disorder; **AND**
3. The member is unable to use or has tried and failed BOTH of the following:
 - a. Lamotrigine immediate-release; **and**
 - b. Lamotrigine chewable tablet; **AND**
4. Lamotrigine ODT is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature; **AND**
5. Clinical chart documentation is provided for review to substantiate the above listed requirements.

For other off-label uses:

1. The member is 18 years of age or older; **AND**
2. The medication is being requested for **ONE** of the following:
 - a. acute treatment of bipolar major depression; **or**
 - b. prophylactic therapy to decrease severity and frequency of short-lasting unilateral neuralgiform headache attacks; **or**
 - c. management of symptoms associated with trigeminal neuralgia; **AND**
3. The member is unable to use or has tried and failed **BOTH** of the following:
 - a. Lamotrigine immediate-release; **and**
 - b. Lamotrigine chewable tablet; **AND**
4. Lamotrigine ODT is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature; **AND**
5. Clinical chart documentation is provided for review to substantiate the above listed requirements.

If the above prior authorization criteria is met, lamotrigine ODT will be approved for up to 12 months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if the member has chart documentation demonstrating a clinical improvement in symptoms since starting the requested medication:

For the treatment of epilepsy:

1. The member has demonstrated a reduction in severity and/or frequency of seizures.

For the treatment of bipolar disorder:

1. The member's condition has improved or stabilized based upon the prescriber's assessment.

For other off-label uses:

1. The member's condition has demonstrated improvement, as validated by clinical assessment.

Experimental or Investigational / Not Medically Necessary

Lamotrigine ODT for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

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